5 Structural requirements

5.1 *The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.*

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 *The laboratory shall identify management that has overall responsibility for the laboratory.*

5.3 *The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.*

5.4 *Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.*

5.5 *The laboratory shall:*

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 *The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:*

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

5.6.3 The laboratory ~~shall designate~~must have (a) Technical Specialist(s) to provide technical guidance to laboratory personnel for each TNI-defined analytical discipline (Asbestos, Microbiology, Radiochemistry, Whole Effluent Toxicity, Inorganic Chemistry – Nonmetals, Inorganic Chemistry – Metals, Organic Chemistry) corresponding to the fields of accreditation listed in the laboratory's scope of accreditation. A single individual may be appointed as the Technical Specialist for one or more TNI-defined analytical disciplines and may also hold additional primary job responsibilities.

Technical specialist(s) must:

a) provide guidance and oversight to laboratory personnel as needed to ensure activities related to the generation of analytical data and test results, including but not limited to method development and validation, procedure development, sample preparation, instrument calibration, sample analysis, quality control, and data reduction comply with the laboratory's quality management system and with relevant regulatory requirements for which the data will be used and

b) have the authority to halt work, repeat work, withhold reports, and resume work as part of the management of nonconforming work, as defined in 7.10. ~~oversee or participate in decisions and actions related to the management of nonconforming work~~, ~~including the authority to authorize 'stop work' requirements~~.

Commented [DB1]: From Jacksonville '25: all good as written

Commented [DB2]: Radiochemistry will be split into several analytical disciplines soon.

Commented [KD3]: I replaced responsibility with guidance and oversight. "responsibility to manage" by common definition implies the technical specialist has supervisory or management responsibility, which is not required. I think oversight is a better description of intent.
I also removed "key personnel" which I know is controversial. In some labs the TS may be key personnel. In a lab like PAS, a role is not key personnel until it is at the Director or Officer level, which the exception of the Quality Manager. We have 1 Chief Technical Officer for our 80+ labs and I think 4 Technical Directors. Tech Spec for TNI are usually bench analysts. Bench analysts are not involved in decisions that affect our business - they are not key personnel, the CTO is. Also the whole concept of key personnel is that here is a deputy to maintain - Section 5.6.5 essentially fulfills the intent of key personnel so I don't think the removal of the statement that TS are key personnel is significant.

Commented [PJ4]: Is this sufficient for giving authority to stop a method?

~~b)~~

5.6.4 A Technical Specialist may be appointed across multiple laboratories, subject to approval by the primary accrediting body. Requests for approval must include a plan outlining how the Technical Specialist will meet the requirements in section 5.6.3 across multiple locations. Records of the accrediting body's approval, including the approved plan, must be maintained.

5.6.5 The laboratory must have a deputy(ies) for the Technical Specialist(s). ~~:~~

~~a)~~ The deputy is not required to meet the qualification requirements of a Technical Specialist.

5.6.6 The deputy must assume the responsibilities of the Technical Specialist when the Technical Specialist is unable to fulfill the duties specified in sections 5.6.3 a) and b) for fifteen (15) consecutive calendar days.

a) ~~When~~ If the deputy has assumed the responsibilities of the Technical Specialist for more than sixty (60) consecutive calendar days, the laboratory must notify the accreditation body in writing and include a plan with a timeline for appointing a qualified Technical Specialist.

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 *All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.*

6.2.2 *The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.*

~~6.2.2.1 Technical Specialist Qualification Documentation and Records~~

~~Laboratory management shall develop a document outlining the required education and experience for a Technical Specialist, however named. The laboratory shall maintain a record showing that each Technical Specialist meets the education and experience requirements. Where coursework is required, the laboratory must retain supporting records that show courses were successfully completed (e.g., certificate, letter, transcript). Section 4 of Modules 3 through 7 may include specific requirements for Technical Specialist qualifications.~~

6.2.2.1 Technical Specialist Qualifications

Technical Specialist qualifications are based on: education and experience, credentialing, or recognition by previous revisions of this Standard~~, and or technical/analytical discipline scope expansion~~.

The laboratory shall maintain a record showing that each Technical Specialist meets the requirements of 6.2.2.2~~The laboratory must maintain records that demonstrate the technical specialist(s) meet(s) the qualifications~~ or exceptions ~~defined below~~of 6.2.2.3. Where coursework is required, the laboratory must retain supporting records that show courses were successfully completed (e.g., certificate, letter, transcript).

6.2.2.2 A technical specialist must meet one set of the following minimum qualifications for each ~~technical/~~analytical discipline for which they are responsible, where the required experience is in the

Commented [DB5]: From Jacksonville '25: Consider providing competency record for Deputy TS to AB.

Commented [DB6R5]: From Jacksonville '25: Instead of b) and c) add a requirement to notify AB when TS cannot fulfill duties within x days along with a plan on how and when the lab will have a TS fulfilling the role.

Commented [DB7]: Question for TNI/Robin: How does this affect a 1-person lab? Is a 1-person lab effectively able to maintain the QMS outlined in this standard?

Commented [DB8]: From Mike Michaud email 2/6/25: I think we need to consider adding a description to define it. Something similar to they must have experience in the area they will be responsible for or must have experience performing the methods they will be responsible for.

Commented [DB9R8]: The deputy will not have qualification requirements, so this is unnecessary.

Commented [DB10]: Consider including in Annex C some information on how a laboratory handles the TS (and maybe deputy) being unable to fulfill the role, even if the 15 days aren't met.

Commented [DB11]: From Jacksonville '25: Change "additional" to "specific"

Commented [DB12]: REMOVE IF WE KEEP the rest of 6.2.2.1

Commented [DB13]: Ensure we are not requiring environmental experience where non-environmental will be just as valuable.

Commented [PJ14]: Requiring our own program and we need to be open to others. We've written a standard that allows us to profit from how it is written. Re-write to be less specific, yet allow other credential types.

Commented [PJ15]: Should this be or?

Commented [BD16]: Update once new analytical discipline scope addition paragraph is complete

Commented [DB17]: Consider adding to Annex C a link to the site that includes equivalency of different country's degrees to USA degrees.

Commented [PJ18]: This doesn't address an Associates Degree, but that's what the Technical Modules reference

corresponding ~~technical/~~analytical discipline(s). In addition, analytical disciplines for Asbestos, Microbiology and Radiochemistry require a relevant technical course.~~:~~

* a master's or doctoral degree and one (1) year of experience,

* a bachelor's degree in a scientific field that includes STEM (science, technology, engineering, math) courses and two (2) years of experience,

* an associates degree in a scientific field that includes STEM courses and three (3) years of experience,

* four (4) college level STEM ~~(science, technology, engineering, math)~~ courses and four (4) years of experience, or

~~* be a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility and have two (2) years of experience, or~~

* ~~TNI~~ technical specialist credential for each ~~technical/~~analytical discipline and one (1) year of experience.

6.2.2.3 Technical Specialist Qualification Options for Exempting Education and Experience Requirements

a) Any person who was ~~formally~~ formerly recognized as a Technical Specialist (however named) based on requirements or exceptions in previous revisions of this Standard will continue to be eligible as Technical Specialist for the same analytical disciplines at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

b) Any person who is an employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility and has two (2) years of laboratory experience is eligible as Technical Specialist.

~~b)~~c) [insert language for Primary AB approval of exempted Technical Specialist]

~~c) Any person who has been credentialed by an organization such as the American Water Works Association (AWWA), the Water Environment Federation (WEF), or The NELAC Institute (TNI) shall be considered to possess the requisite qualifications to be eligible as Technical Specialist.~~

d) ~~If a laboratory seeks accreditation for a method in a TNI-defined analytical discipline that is not currently on the laboratory's scope of accreditation, the person who is assigned responsibility for demonstrating performance of a method (installation documentation, method validation or verification, DOC, PT performance, etc.) is eligible to serve as Technical Specialist for that method.~~

Commented [BD19]: To qualify as a technical specialist, a candidate must have experience in the analytical disciplines for the area of responsibility and the education or training listed in one of the options listed below:

Commented [DB20]: STEM field

Commented [PJ21]: bachelor's degree that includes STEM (Science, Technology, Engineering, Mathematics) courses.

Commented [PJ22]: bachelor's degree that includes STEM (Science, Technology, Engineering, Mathematics) courses.

Commented [PJ23]: Seems like Associates Degree ought to be the next step in this set of options. Why is a Bachelors Degree the same as a valid treatment plant operator's license (each need it plus 2 years of experience)?

Commented [PJ24]: Did Bob determine if this is an ANSI conflict for us? Confer with Matt Sica and Nicolas Slawson

Commented [PJ25R24]: Not a conflict per Bob - delete TNI and we should be good.

Commented [DB26]: From Jacksonville '25 (Elizabeth Lesold): Potential conflict because some TP Operator certification (b) and credentialing (c) may overlap enough to cause confusion. For b) must have experience; what about for c)?

Commented [DB27]: From Jacksonville '25: Add that appropriate records must be maintained to show previous recognition as TS."

Commented [DB28]: From Jacksonville '25: Is this lab experience or experience as an operator? Or does it matter?

Commented [DB29]: Should we add analytical discipline to this experience?

Commented [DB30]: AC Feedback email 2/11/25: Regarding credentials, this seems like this could be a show stopper for several ABs present. Concern was brought up that we are including an unknown or future concept into the standard. Concern was brought up that no one was actually aware of what a WEF or AWWA credential actually was. There was also concern brought up that the credentialing concept would be used as a complete replacement for education, classwork, ar ... [1]

Commented [DB31R30]: From Jacksonville '25: change to "legitimate organization" or "TNI recognized credentialing organization"

Commented [DB32R30]: From Jacksonville '25: Better to say "credentialed by an authoritative body" or som ... [2]

Commented [DB33]: AC Feedback email 2/11/25: The way this is written on the slide indicates that a laboratory could apply for a method in an analytical discipline ... [3]

Commented [DB34R33]: From Jacksonville '25: Tracking TS by method is not possible. Could the end be "the TS for that analytical discipline"?

Commented [DB35R33]: From Jacksonville '25: This section could probably be removed since it was ad ... [4]

Page 3: [1] Commented [DB30] **Bond, Debbie** **3/7/25 7:52:00 AM**

AC Feedback email 2/11/25: Regarding credentials, this seems like this could be a show stopper for several ABs present. Concern was brought up that we are including an unknown or future concept into the standard. Concern was brought up that no one was actually aware of what a WEF or AWWA credential actually was. There was also concern brought up that the credentialing concept would be used as a complete replacement for education, classwork, and experience. Several ABS brought up the idea that it could possibly be used to replace experience or education to some extent.

Page 3: [2] Commented [DB32R30] **Bond, Debbie** **3/12/25 2:04:00 PM**

From Jacksonville '25: Better to say "credentialed by an authoritative body" or something like that than to call out specific organizations including TNI (see also how FSMO sections are worded).

Page 3: [3] Commented [DB33] **Bond, Debbie** **3/7/25 7:52:00 AM**

AC Feedback email 2/11/25: The way this is written on the slide indicates that a laboratory could apply for a method in an analytical discipline that they are not accredited for and be allowed to be technical specialist without any experience. For example they could apply for Organics when only being accredited for Micro, without any experience except setting up the method What we assume it should say is that a laboratory can apply for a method in an analytical discipline that they are accredited for.

Page 3: [4] Commented [DB35R33] **Bond, Debbie** **3/12/25 2:05:00 PM**

From Jacksonville '25: This section could probably be removed since it was added when we were looking at technologies instead of analytical disciplines.